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Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1 of 4

**Complete if Known**

Application Number	10/709,870
Filing Date	June 2, 2004
First Named Inventor	Mitchell I. Kirschner
Art Unit	1616
Examiner Name	Frank I. Choi
Attorney Docket Number	718689.78

**U.S. PATENT DOCUMENTS**

Examiner Initials'	Cite No. <sup>1</sup>	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)				
	A1	US- 2,491,452		12-13-1949	Kern et al.	
	A2	US- 4,656,028		04-07-1987	Cuca, Robert C.	
	A3	US- 4,690,816		09-01-1997	Paradissis et al.	
	A4	US- 4,772,472		09-20-1988	Schönmann et al.	
	A5	US- 4,874,629		10-17-1989	Chang et al.	
	A6	US- 4,891,172		01-2-1990	Matsushita et al.	
	A7	US- 4,935,243		06-19-1990	Borkan et al.	
	A8	US- 5,071,643		12-10-1991	Yu et al.	
	A9	US- 5,141,961		08-25-1992	Coapman, Scott D.	
	A10	US- 5,200,191		04-06-1993	Steele et al.	
	A11	US- 5,246,635		09-21-1993	Ratko et al.	
	A12	US- 5,360,615		11-01-1994	Yu et al.	
	A13	US- 5,422,160		06-06-1995	Ratko et al.	
	A14	US- 5,565,214		10-15-1996	Zambo et al.	
	A15	US- 5,641,512		06-24-1997	Cimiluca, Paul A.	
	A16	US- 5,827,535		10-27-1998	Stone, Dan D.	
	A17	US- 5,869,084		02-09-1999	Paradissis et al.	
	A18	US- 6,077,828		06-20-2000	Abbruzzese et al.	
	A19	US- 6,258,846		07-10-2001	Hermelin et al.	
	A20	US- 6,346,231		02-12-2002	Opheim, Joar	
	A21	US- 6,471,969		10-29-2002	Schlachter et al.	
	A22	US- 2005/0037065 A1		02-17-2005	Kirschner et al.	

Examiner Signature		Date Considered	
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			Filing Date	June 2, 2004	
			First Named Inventor	Mitchell I. Kirschner	
			Art Unit	1616	
Examiner Name	Frank I. Choi				
Sheet	2	of	4	Attorney Docket Number	718689.78

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				
	B1	JP 54-35210	03-15-1979	Seo et al.		
	B2	GB 2,223,943	04-25-1990	Tillotts Pharmaceutical AG		
	B3	GB 2,254,556	10-14-1992	Fisons plc		
	B4	JP 5-139959	06-08-1993	EISAI Co. LTD.		
	B5	WO 9704668 A2	02-13-1997	Schlachter et al.		

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	C1	STN/CAS Online, file CAPLUS, Acc. No. 1989:462736, Doc. No. 91:62736; Seo et al.; "Soft capsules of unsaponifiable substances of vegetable oils"; JP 54035210 A2; Abstract.	
	C2	Database CAPLUS on STN, No. 1993:525229; KATO et al.; "Soft Capsules containing water-soluble pharmaceuticals"; JP 05139959 A (Kato et al.) June 8, 1993, Abstract.	
	C3	STN/CAS online, file PROMT, Acc. No. 97:437691; Mont, "Brittle and Twisted;" Chemist & Druggist (Text); July 5, 1997; page 1.	
	C4	STN/CAS online, file PROMT, Acc. No. 83:40219; "Manufacturing Chemist & Aerosol News"; Abstract; March 1983; pages 56-591; Abstract.	
	C5	VITAMIN RESEARCH DEPT.; "Can adults adequately convert alpha-linolenic acid (18:3n-3) to eicosapentaenoic acid (20:5n-3) and docosahexaenoic acid (22:6n-3)?" Int J. Vitam Nutr Res (Text); 1998; 68(3): 159-73; F. Hoffman-Roche Ltd; Basel, Switzerland; Text.	

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	C6	FAN, YY & CHAPKIN, RS; "Importance of dietary gamma-linolenic acid in human health and nutrition"; Int. J. Vitam Nutr Res. (Text); Sept. 1998; 128(9): 1411-4; Faculty of Nutrition, Molecular & Cell Biology Group, Texas A&M University; Texas.	
	C7	MEYDANI ET AL.; "Food use and health effects of soybean and sunflower oils"; J Am Coll Nutr (Text); October 1991; 10(5): 406-28; USDA Human Nutrition Research Center on Aging, Boston, Massachusetts.	
	C8	Remington's Pharmaceutical Sciences; 1985; page 328; 17th Edition.	
	C9	FOOD AND DRUG ADMINISTRATION; "Amino Acid Supplements: What you need to know"; <a href="http://vanderbiltowc.wellsources.com">http://vanderbiltowc.wellsources.com</a> ; August 2004; 3 pages; Food and Drug Administration.	
	C10	Physicians' Desk Reference; 1999; Page 3128 53d Ed.	
	C11	Physicians' Desk Reference; 1999; Page 3163; 53d Ed.	
	C12	Physicians' Desk Reference; 1999; Page 3212; 53d Ed.	
	C13	Physicians' Desk Reference; 1999; Pgs. 2811-2812; 53d Ed.	
	C14	Physicians' Desk Reference; 1999; Page 1011; 53d Ed.	
	C15	Physicians' Desk Reference; 1999; Pages 1522-3; 53d Ed.	
	C16	Physicians' Desk Reference; 1999; Page 1692; 53d Ed.	
	C17	Physicians' Desk Reference; 1999; Page 2802; 53d Ed.	
	C18	Physicians' Desk Reference; 1999; Pages 2916-7; 53d Ed.	
	C19	Physicians' Desk Reference; 1999; Pages 2917-8; 53d Ed.	
	C20	The Merck Manual; 1992; Page 749; 16 <sup>th</sup> Ed.	
	C21	The Merck Manual; 1992; Pages 1850-1866; 16 <sup>th</sup> Ed.	
	C22	OLANS, et al.; "Gastroesophageal Reflux. In Pregnancy"; Gastrointest Endosc. Clin. N. Am. 4(4); 1994; 4 Pages 699-712.	

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	C23	BROUSSARD, ET AL.; "Treating Gastroesophageal Reflux Disease during Pregnancy and Lactation: What are the safest therapy options"; Drug Safe 19(4); 1998; Pages 325-337.	
	C24	Physicians' Desk Reference; 1999; Pages 2526-2527; 53d Ed.	
	C25	KATZ, ET AL.; "Gastroesophageal Reflux Disease during Pregnancy"; Gastroenterol. Clin. North Am. 27(1); 1998; Pages 153-167.	
	C26	NEBEL, ET AL.; "Symptomatic Gastroesophageal Reflux; Incidence and Precipitating Factors"; Am. J. Dig. Dis. 21(11); 1976; Pages 953-956.	
	C27	MORTON, KOUSEN, M.D.; "Treating Nausea and Vomiting in Pregnancy"; Am. Family Physician 48(7); 1993; Pages 1279-1284.	
	C28	"Understanding Nutrition"; Whitney and Rolfes Eds.; 1993; Pages 479-480; 6 <sup>th</sup> Ed.	
	C29	SCHORAH, ET AL.; "Importance of Adequate Folate Nutrition in Embryonic and Early Fetal Development Vitamins and Minerals in Pregnancy and Lactation"; Berger Ed.; 1988; Pages 167-176.; Vol. 16.	
	C30	SMITHELLS, ET AL.; "Vitamin Deficiencies and Neural Tube Defects"; Arch. Dis. Child; 1976 Pages 51:944-950.	
	C31	"Van Nostrand's Scientific Encyclopedia"; 1983; Page 2891; 6 <sup>th</sup> Ed.	
	C32	OTTO, S. J., ET AL.; "Maternal and Neonatal Essential Fatty Acid Status in Phospholipids: An International Comparative Study, European Journal of Clinical Nutrition"; April 1997; Pages 232-242; Vol. 51 #4.	

Examiner Signature	/Frank Choi/	Date Considered	04/15/2008
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